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May 9, 2005

Mail Stop Appeal Brief - Patents  
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Re: **Application Serial No.:** 09/428,036  
**Confirmation No.:** 4122  
**Art Unit:** 3626 (Examiner Robert W. Morgan)  
**Appellants:** Kevin H. Newton, et al.  
**Title:** Method of Tracking and Dispensing  
Medical Items to Patients through  
Self Service Delivery System  
**Docket No.:** D-1124

Sir:

Please find enclosed a Reply Brief pursuant to 37 C.F.R. § 41.41 in response to the Examiner's Answer dated April 6, 2005 for filing in the above-referenced application.

No fee is deemed required. However, the Commissioner is authorized to charge any necessary fee associated with the filing of this Reply Brief and any other fee due to Deposit Account 10-0637.

Very truly yours,

Ralph E. Jocke  
Reg. No. 31,029

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D-1124

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of	)	
Kevin H. Newton, et al.	)	
	)	
Application No.: 09/428,036	)	Art Unit 3626
	)	
Confirmation No.: 4122	)	
	)	Patent Examiner
Filed: October 27, 1999	)	Robert W. Morgan
	)	
Title: Method of Tracking and	)	
Dispensing Medical Items to	)	
Patients through Self Service	)	
Delivery System	)	

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PO Box 1450  
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**REPLY BRIEF OF APPELLANTS  
PURSUANT TO 37 C.F.R. § 41.41**

Sir:

The Appellants hereby submit their Reply Brief pursuant to 37 C.F.R. § 41.41 concerning the above-referenced Application. This Reply Brief is in response to the Examiner's Answer ("Answer") dated April 6, 2005.

## **REAL PARTY IN INTEREST**

The Assignee of all right, title and interest to the above-referenced Application is  
Automated Technologies, Inc., a Pennsylvania corporation.

## STATUS OF CLAIMS

Claims 1-45 are pending in the Application.

Claims rejected: 1-45

Claims allowed: none

Claims confirmed: none

Claims withdrawn: none

Claims objected to: none

Claims canceled: none

## **GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

The questions presented in this appeal are:

- 1). Whether Appellants' claims 1, 10-23, and 26-27 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by Kraft, et al. (U.S. 5,502,944) ("Kraft").
- 2). Whether Appellants' claims 2 and 9 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Liff, et al. (U.S. 5,797,515) ("Liff").
- 3). Whether Appellants' claims 3-8 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Liff and an Official Notice.
- 4). Whether Appellants' claims 24-25 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of an Official Notice.
- 5). Whether Appellants' claims 28-31, 34-39, and 42-44 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman, et al. (U.S. 5,036,416).
- 6). Whether Appellants' claims 32-33, 40-41, and 45 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraft in view of Kaufman and Cummings, Jr. (U.S. 5,301,105) ("Cummings").

## ARGUMENT

The rejections set forth in the Answer (on pages 3-28) appear to be identical to the grounds previously presented in the Office Action dated January 14, 2004, from which appeal was reinstated. Thus, Appellants respectfully submit that the rejections set forth in the Answer have already been fully addressed in Appellants' Supplemental Appeal Brief filed on April 12, 2004. Therefore, please note Appellants' previous (Supplemental Appeal Brief) arguments regarding all the issues of record.

The Answer includes a "Response to Argument" section beginning on page 28. However, this section provides no new support for the rejections. Most of the this section's "answer" consists of merely repeating the cited sections of the references already presented in the "Grounds of Rejection" section of the Answer (which cited reference sections were already a repeat of the cited reference sections presented in the Office Action dated January 14, 2004). Thus, Appellants respectfully submit that the Office's "answer" has already been fully addressed in Appellants' Supplemental Appeal Brief. The Office still has not provided any evidence of anticipation nor any factual support for a *prima facie* conclusion of obviousness.

Also, the "Response to Argument" section of the Answer only notes a portion of the many arguments made in the Supplemental Appeal Brief. Regardless, Appellants take this opportunity to reply to those arguments actually noted by the Answer (listed therein as A-Q) and to reiterate some of the reasons why the rejections should be withdrawn.

(A)

Appellants have already presented, in the Supplemental Appeal Brief, many valid reasons why Kraft does not anticipate claim 1. For example, Kraft at least does not teach step (e). Particularly note Appellants' remarks at pages 12-16 of the Supplemental Appeal Brief.

(B)

The Office has not addressed Appellants' arguments set forth in the Supplemental Appeal Brief with regard to claims 10-23 and 26-27. Rather, the Answer merely repeats the cited sections of Kraft already presented at Answer pages 4-8 (which was a repeat of the cited sections presented in the Office Action dated January 14, 2004). Thus, the Answer's reliance on Kraft has already been fully addressed in Appellants' Supplemental Appeal Brief.

The Answer indicates that the Appellants have presented allegations that are merely conclusory, not supported by any evidence, and fail to provide any reasonable analysis of the applied reference. However, the burden of showing a valid case of anticipation remains with the Office. Appellants are not required to prove non-anticipation. That is, the Appellants are not required to prove patentability. Conversely, it is the Office which must establish a valid rejection under the law. Otherwise, the Office is legally required to issue a patent. Nevertheless, Appellants have presented valid reasons discrediting the Office's allegations of anticipation regarding claims 10-23 and 26-27. Particularly note Appellants' remarks at pages 16-20 of the Supplemental Appeal Brief.

(C)

The Answer is silent as to which claim(s) is being addressed or the specific location in Supplemental Appeal Brief of the indicated argument. Thus, the Answer's reliance on col. 4, lines 62-64, of Liff is incomprehensible.

The Answer is also silent as to where the Appellants stated that "the motivation to make modifications must be expressly articulated *within the references themselves*", as alleged (at Answer page 32). The "Applicable Legal Standards" section (at pages 7-9) of the Supplemental Appeal Brief simply indicates that the motivation to combine prior art features must be clearly and particularly identified in the prior art.

The Answer at pages 31-32 cites many old legal cases. The absence of newer citations, e.g., *In re Zurko*, 258 F.3d 1379, 59 USPQ2d 1693 (Fed. Cir. 2001) and *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002), which take precedence over many of the relied upon old citations, is noted. The Examiner's reliance on old citations is an example of the Office's unfair interpretation of the current issues, laws, and rules, and is further reflective of all the impropriety of the rejections on appeal. Also, the Appellants respectively disagree with the Examiner's self judgement in the Answer (at page 32, lines 1-3) that "he has at least satisfied the burden of presenting a *prima facie* case of obviousness". This disagreement is one of the many reasons why this application is under appeal.

(D) and (E)

The issue is whether a secondary reference, in order to be a legally available modifying reference, has to be prior art to the entire claim or only a small portion thereof. The Office itself has admitted that Liff does not constitute prior art to the subject matter of claim 1, as discussed in more detail at pages 21-22 of the Supplemental Appeal Brief. Further discussed in the Supplemental Appeal Brief (at pages 21-22), Liff also does not constitute prior art to the subject matter of claims 2-9. Appellants respectfully submit that if Liff isn't prior art to the claim 1 features, then how can its alleged teachings be used to modify these same features? In other



words, how can Liff modify features having a date prior to the availability of Liff? Because Liff wasn't prior art at the time of the claim 1 features, Liff also wasn't available to modify these features. If Liff isn't prior art to independent claim 1, then Liff cannot be prior art to dependent claims 2-9.

Even if it were somehow possible for Liff to constitute prior art to claims 2-9, Appellants have shown in the Supplemental Appeal Brief that the relied upon teachings of Liff still do not render the claims obvious.

(F)

As discussed in more detail in the Supplemental Appeal Brief (at pages 22 and 27-28), the reliance on Liff for the features of claims 7-8 is improper. The Examiner can't on one hand admit that the availability of Liff as prior art is limited to specific subject matter, yet on the other hand liberally apply Liff to claims (e.g., claims 7-8) having additional subject matter.

Regardless, the Answer (on page 13, lines 1-3) admits that Kraft/Liff fails to teach the recited features and relationships of claims 7-8. That is, the Answer admits that Kraft/Liff do not teach or suggest outputting indicia representative of a co-pay amount through an output device adjacent to a dispenser. The rejection of claims 7-8 relies on Kraft/Liff alone (without any Official Notice). The Action then apparently alleges that it would be obvious to combine the teachings of Kraft and Liff. The Appellants respectively disagree. Nevertheless, the rejection is based on Kraft and Liff alone. Even if the teachings of Kraft and Liff were combined as alleged, Kraft/Liff would still fail to teach the recited features and relationships, which the Action admits.

*In re Zurko, supra. In re Lee, supra.*

(G)

The Answer is silent as to which claim(s) is being addressed or the specific location in Supplemental Appeal Brief of the indicated argument. It appears that the Answer is referring to claim 2. However, the Answer's allegation of information in Liff being "verified" is incomprehensible, as claim 2 does not contain such language. Regardless, the Answer (on page 9, last paragraph) admits that Kraft does not teach or suggest data representative of a benefit plan, or payment rules associated with the benefit plan, or charging for a dispensed medical item in accordance with the payment rules.

As discussed in more detail in the Supplemental Appeal Brief (at page 23), Liff cannot alleviate the admitted deficiencies of Kraft as it does not teach or suggest the recited features which are not found in Kraft. For example, Figure 12 of Liff is a process performed by a pharmacy technician. There is no indication that the relied upon step of adjudication (286) requires storing (in the data store of claim 1) benefit plan data or payment rules. Also, the Office's misinterprets Liff's statement that "a patients's insurance information is automatically verified". In Liff, the patient presents a prescription to a pharmacy technician at an RCD unit. The technician (apparently manually) prepares the relevant data (including the adjudication information), and then transmits this data to the pharmacist workstation (571) so the adjudication can take place in a third city (588).

(H)

The Appellants respectively disagree with the Examiner's allegation (at Answer page 35) that "Appellant's present rebuttal is moot" regarding the challenge to the Official Notice because the traversal was not timely made "during examination". Contrary to the Examiner's opinion,

examination has not yet ended. Nor is an Applicant required to present *all* arguments in response to an Office Action, especially when one argument will suffice. An Appeal Brief may include additional arguments. "Any arguments or authorities not included *in the brief or reply brief* filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown" (37 C.F.R. § 41.37). Appellant's right to present rebuttal arguments at the time of appeal cannot be denied by an Examiner, especially as a means to deny a patent.

The Answer, for the *first* time, relies on Doyle (US 5,070,452) for the Official Notice assertion regarding the rejection of claims 3-6. However, the Action (at page 11, last paragraph) admits that Kraft/Liff fail to teach or suggest reading a credit or debit card with a card reading device adjacent a medical item dispenser, wherein the card reading device is in operative connection with the computer, and charging an account associated with the credit or debit card. Where does Doyle teach or suggest reading a credit or debit card with a card reading device adjacent a *medical item dispenser* (e.g., claim 3)? Where does Doyle discuss a medical item dispenser? Likewise, the Answer, for the *first* time, relies on Portwood (US 5,950,630) for the Official Notice assertion regarding the rejection of claims 24-25. Where does Portwood teach or suggest contacting the *patient* (e.g., claim 24) with regard to abnormalities found regarding verification of pharmaceutical data, as alleged? The basis of the rejection does not include Doyle nor Portwood. Nor are Doyle and Portwood of record. Appellants respectfully submit that Office's reliance on Doyle and Portwood goes beyond the scope of the initial Official Notice assertions. Thus, the relied upon sections of Doyle and Portwood are not admissible evidence.

(I)

The Office has not addressed Appellants' arguments set forth in the Supplemental Appeal Brief with regard to claims 4-8 and 24-25. Rather, the Answer merely repeats the cited sections of Kraft and Liff already presented at Answer pages 12-14 (which was a repeat of the cited sections presented in the Office Action dated January 14, 2004). Thus, the Answer's reliance on these references has already been fully addressed in Appellants' Supplemental Appeal Brief.

Again, in spite of the Examiner's opinion, the Appellants are not required to prove patentability. Conversely, it is the Office which must establish a valid *prima facie* case of obviousness under the law. If the Office does not produce a *prima facie* case (which is the current situation), then the Appellants are under no obligation to submit a showing of nonobviousness. MPEP § 2142. Nevertheless, Appellants have shown that a *prima facie* case of obviousness has not been established.

(J) and (K)

The Answer is silent as to which claim(s) is being addressed or the specific location in the Supplemental Appeal Brief of the indicated argument. As best understood, the Office is referring to Appellants' arguments regarding the rejection of claim 28.

The Answer admits (on page 15) that Kraft fails to disclose or suggest a patient-accessible self-service medical item dispenser. In Kraft it is a nurse which uses the dispenser (12). The Answer concurs (on page 15) that in Kraft it is the nurse, not the patient, which uses the dispenser (12) having a controller (34). Kraft is directed to providing secure medical dispensing "to nurses in a hospital setting" (col. 1, lines 5-8).

The Answer (on page 38) repeats the alleged description of Kaufman already found on page 15. The Office alleges that an individual patient in Kaufman enters information to access medication. However, Kaufman is directed to medical dispensing in a "home, outside the support system of a hospital", and without the "supervision of medical personnel" (col. 1, lines 10-14). If a patient can use Kaufman's dispenser, then they don't need to be in Kraft's hospital. The evidence of record does not teach or suggest a patient accessing their own medication from a dispenser in a hospital. As is well known, the dispensing and taking of prescribed medical items in a hospital is highly controlled. Kraft requires a dispenser that fits into this highly controlled (secure) hospital environment. Kraft's hospital system requires and provides security against unauthorized personnel (especially patients) gaining access to medicine in the dispenser (12). Even a nurse must enter authorized identification, such as a secret password, in order to obtain medication from the dispenser (12) (col. 5, lines 8-11). Thus, Kraft explicitly teaches against using a patient-accessible self-service medical item dispenser to dispense a medical item to a patient, especially a prescribed medical item.

Nevertheless, the Office asserts that it would be obvious (in view of Kaufman's non-secured, non-hospital, in-home dispenser) to change Kraft's nurse-accessible secured hospital dispenser into a patient-accessible self-service medical item dispenser. As discussed in more detail in the Supplemental Appeal Brief (at page 30), it would not have been obvious to one having ordinary skill in the art to have modified Kraft with the teaching of Kaufman in the manner reasoned by the Examiner to have produced the recited invention of claim 28.

The Answer's remarks that the combination "purported by the Examiner does not discourage using authorization identification for dispensing medication from a dispenser in a

secure hospital environment", permits either "receiving input from the physician" or "the nurse enters commands" are not pertinent to the recited subject matter of claim 28. The claim recites that the dispenser comprises a *patient*-accessible self-service medical item dispenser, not a *physician/nurse*-accessible self-service medical item dispenser.

(L)

The Office has not addressed Appellants' arguments set forth in the Supplemental Appeal Brief with regard to claims 29-31. Rather, the Answer merely repeats the cited sections of Kraft and Kaufman already presented at Answer page 16 (which was a repeat of the cited sections presented in the Office Action dated January 14, 2004). Thus, the Answer's reliance on these references has already been fully addressed in Appellants' Supplemental Appeal Brief.

Again, in spite of the Examiner's opinion, the Appellants are not required to prove patentability. Conversely, it is the Office which must establish a valid *prima facie* case of obviousness under the law. If the Office does not produce a *prima facie* case (which is the current situation), then the Appellants are under no obligation to submit a showing of nonobviousness. MPEP § 2142. Nevertheless, Appellants have shown that a *prima facie* case of obviousness has not been established.

(M)

The Office has not addressed Appellants' arguments set forth in the Supplemental Appeal Brief with regard to claim 34. Rather, the Answer merely repeats the cited sections of Kraft already presented at Answer page 17 (which was a repeat of the cited sections presented in the Office Action dated January 14, 2004). Thus, the Answer's reliance on these references has already been fully addressed in Appellants' Supplemental Appeal Brief.

Where does the relied upon Kraft reference teach or suggest verifying with a dispenser that the requested medical item was dispensed (step d)? Where does the relied upon Kraft reference teach or suggest including in a data store data linking the verified dispensed medical item to that patient (step e)?

Kraft does not teach or suggest recited steps (d) or (e) at col. 5, lines 47-55. In response to a nurse's dispense request, Kraft's system controller (34) records a dispense for a patient (col. 5, lines 6-7). That is, an *unverified* dispense is recorded. Note Kraft's references to the recording occurring as "medication is dispensed" (col. 5, lines 6-7) and as "medications are dispensed" (col. 5, lines 49-52). Even Kraft's database is updated as medication is (supposedly) being dispensed (col. 6, lines 32-34). How can data that a medical item was verified as *dispensed* be recorded in Kraft when recordation in Kraft occurs before the dispensing is even complete? At best, Kraft records a dispense responsive to a dispense request, not responsive to execution of an actual dispensing.

Nor does Kraft teach or suggest recited steps (d) or (e) at col. 7, lines 26-34. The relied upon vision subsystem (44) comprises singulation optics (124) and a container identification optics (126). The container identification optics (126) is for reading the label of a bulk medication container (90, 130). The singulation optics (124) ensures that a single medication is properly positioned *to be* dispensed from the bulk container (90, 130) (col. 7, lines 38-43; col. 8, lines 13-15 and 39-67). It follows that Kraft does not teach or suggest including in a data store, data linking the *verified dispensed* medical item to that patient (i.e., claim 34, step e). Also note Appellant's additional applicable remarks found in support of the patentability of claim 1.

(N)

The Office has not addressed Appellants' arguments set forth in the Supplemental Appeal Brief with regard to claims 35-39 and 42-44. Rather, the Answer merely repeats the cited sections of Kraft and Kaufman already presented at Answer pages 18-22 (which was a repeat of the cited sections presented in the Office Action dated January 14, 2004). Thus, the Answer's reliance on these references has already been fully addressed in Appellants' Supplemental Appeal Brief.

Again, in spite of the Examiner's opinion, the Appellants are not required to prove patentability. The Office must establish a valid *prima facie* case of obviousness under the law. If the Office does not produce a *prima facie* case (which is the current situation), then the Appellants are under no obligation to submit a showing of nonobviousness. Nevertheless, Appellants have shown that a *prima facie* case of obviousness has not been established.

(O)

The Office has not addressed Appellants' arguments set forth in the Supplemental Appeal Brief with regard to claim 32. Rather, the Answer merely repeats the cited sections of Kraft, Kaufman, and Cummings already presented at Answer pages 22-23 (which was a repeat of the cited sections presented in the Office Action dated January 14, 2004). Thus, the Answer's reliance on these references has already been fully addressed in Appellants' Supplemental Appeal Brief.

The Answer ignores Appellants' arguments (at page 40, first paragraph) that claim 32 depends from claim 2, that Liff was relied upon by the Office to reject claim 2, and that the rejection of claim 32 is not valid because of the absence of the previously relied upon Liff.



(P)

The Office has not addressed Appellants' arguments set forth in the Supplemental Appeal Brief with regard to claims 33 and 40-41. Rather, the Answer merely repeats the cited sections of Kraft, Kaufman, and Cummings already presented at Answer pages 24-25 (which was a repeat of the cited sections presented in the Office Action dated January 14, 2004). Thus, the Answer's reliance on these references has already been fully addressed in Appellants' Supplemental Appeal Brief.

Again, in spite of the Examiner's opinion, the Appellants are not required to prove patentability. The Office must establish a valid *prima facie* case of obviousness under the law. If the Office does not produce a *prima facie* case (which is the current situation), then the Appellants are under no obligation to submit a showing of nonobviousness. Nevertheless, Appellants have shown that a *prima facie* case of obviousness has not been established.

(Q)

The Office has not addressed Appellants' arguments set forth in the Supplemental Appeal Brief with regard to claim 45. Rather, the Answer merely repeats the cited sections of Kraft, Kaufman, and Cummings already presented at Answer pages 25-28 (which was a repeat of the cited sections presented in the Office Action dated January 14, 2004). Thus, the Answer's reliance on these references has already been fully addressed in Appellants' Supplemental Appeal Brief.

As discussed in more detail in the Supplemental Appeal Brief, Cummings cannot alleviate the admitted and discussed deficiencies in Kraft/Kaufman. Cummings is directed to a health care management system. Cummings is not directed to a medical item dispenser. Cummings is non analogous art.

The Answer admits (on page 27) that Kraft/Kaufman fail to disclose or suggest step (d). This step includes reading a credit or debit card with a card reader device *of a patient-accessible self service medical item dispenser*. The Answer relies on Cummings to teach step (d). However, as discussed in the Supplemental Appeal Brief, Cummings' terminal (11a-11c) is not a medical item *dispenser*, especially a patient-accessible self-service medical item dispenser. Cummings does not read a credit or debit card with a card reader device *of a medical item dispenser*. It follows that Cummings does not teach or suggest step (d). The failure of the relied upon Cummings teaching, in light of the Answer's admitted failure of Kraft/Kaufman to teach or suggest step (d), provides evidence that the Office has not established a *prima facie* showing of obviousness.

Additional reasons why the Office has not established a *prima facie* showing of obviousness with regard to claim 45 are presented in the Supplemental Appeal Brief. For example, Kraft/Kaufman/Cummings also do not teach or suggest the step (i) features of including in at least one data store, data linking each of the patient, the verified dispensed medical item type, and the location of the dispensing of the verified dispensed medical item type. Again, the Office has not established a *prima facie* showing of obviousness.

For sake of brevity and to avoid further repetition of the Supplemental Appeal Brief, attention is again directed thereto for additional reasons as to why the references do not anticipate nor render obvious the appealed claims. More detailed remarks regarding all the issues of record, including support for the patentability of each claim, can be found in the Supplemental Appeal Brief.

## CONCLUSION

Each of Appellants' pending claims specifically recites features, relationships, and steps that are neither disclosed nor suggested in the applied prior art. Furthermore, the applied prior art is devoid of any teaching, suggestion, or motivation for combining features of the applied prior art so as to produce the recited invention. For these reasons it is respectfully submitted that all the pending claims are allowable.

Respectfully submitted,



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